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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,887	01/07/2002	James D. Jacobson	EIP-5784 (1417GP657)	8858

7590 03/10/2005

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EXAMINER

HAN, MARK K

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,887

Applicant(s)

JACOBSON ET AL.

Examiner

Mark K Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11, 13-17, 19-22, 24-45 and 47-73 is/are pending in the application.
- 4a) Of the above claim(s) 24-29, 32-44, 51-53, 56, 60, 61 and 68-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 13-17, 19-22, 30, 31, 45, 47-50, 54, 55, 57-59 and 62-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I (claims 1-2, 7-11, 13-17, 19-22, 30, 31, 45, 47-50, 54, 55, 57-59 and 62-67 in the reply filed on 06 October 2003 is acknowledged.
2. Claims 24-29, 32-44, 51-53, 56, 60, 61 and 68-73 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06 October 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 7-11, 13, 14, 16, 17, 57-59, 62, 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,723,086 to Bassuk et al. (hereinafter "Bassuk").

In reference to claims 1, 11, 16 and 57, Bassuk shows a length of tube 126 and a MEMS element 64. See Figure 3. Bassuk shows a controller 92. See also col. 6, lines 7-14. The controller is considered to be detachable.

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In reference to claims 4 and 21, Bassuk shows a flow valve 74, 80 and 86.

In reference to claim 7, Bassuk shows an information storage. See col. 6, lines 59-62.

In reference to claim 8, Bassuk shows a display 52.

In reference to claims 9 and 59, Bassuk shows a means for network communication 34.

In reference to claim 10, Bassuk shows a means for automated control 92.

In reference to claim 11, the tubing and MEMS element are considered to be disposable.

In reference to claims 13 and 17, Bassuk shows a power source. See col. 7, lines 64-66

In reference to claim 14, the power source is considered to be disposable.

In reference to claim 58, Bassuk shows an information storage and display.

In reference to claim 62, Bassuk shows a length of tube, a MEMS element, means for connecting and a means for controlling fluid flow.

In reference to claim 66, Bassuk shows a MEMS flow valve 74, 80 and 86.

In reference to claim 67, Bassuk shows a means for supplying power.

4. Claims 1, 3, 5, 7-11, 16, 22 and 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,733,256 to Costin.

In reference to claims 1, 16 and 57, Costin shows a length of tube ("infusion conduit") and a MEMS element ("pressure & flow sensors"). Costin shows a controller ("microprocessor control"). See Figure 8 and col. 10, lines 19-22. The controller is considered to be detachable.

In reference to claim 3, Costin shows a flow sensor.

In reference to claim 5, Costin shows a pressure sensor.

In reference to claim 7, Costin shows a means for storing information (same means that stores "software").

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In reference to claim 8, Costin shows a means for displaying information (“user interface”).

In reference to claims 9 and 59, Costin shows a means for network communication.

In reference to claim 10, Costin shows a means for automated control and interrogation.

In reference to claim 11, the tubing and MEMS element are considered to be disposable.

In reference to claim 58, Costin shows a means for storing and displaying infusion data.

5. Claims 1, 2, 11, 13-17, 19-22, 30, 31, 45, 47-50, 54,, 55, 57, 62, 63 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,692,481 to Guerrero.

In reference to claims 1, 16, 19 and 30, Guerrero shows a length of tube 90 and a MEMS element 200. See Figure 4. See also col. 4, lines 59-65 and col. 10, lines 35-44. Guerrero shows a controller 220. The controller is considered to be detachable.

In reference to claim 11, the tube and MEMS element are considered to be disposable.

In reference to claims 13 and 17, Guerrero shows a power source 210.

In reference to claim 14, the power source is considered to be disposable.

In reference to claims 2, 15, 19 and 23, MEMS element 200 is a pump. Guerrero also shows an access device 30.

In reference to claim 30, Guerrero shows a tube 90, a MEMS pump element 200 and a power source 210.

In reference to claim 31, the power source is considered to be detachable.

In reference to claims 45, 47-50, 54 and 55, Guerrero discloses the claimed method. See col. 8, line 53 through col. 9, line 30.

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In reference to claims 47 and 55, it is considered that discarding the tubing and MEMS pump after use to be inherently part of the method disclosed in the patent.

In reference to claim 54, the step of calibrating is considered to be inherently part of the method disclosed in the patent.

In reference to claim 62, Guerrero shows a length of tube 90, a MEMS element 200, a means for connecting a first end to a container and a means for controlling fluid flow 220.

In reference to claim 63, Guerrero the MEMS element is a pump 200.

In reference to claim 67, Guerrero shows a means for supplying power 210.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassuk in view of Costin.

Bassuk shows the claimed invention as shown above except for flow and pressure sensors. Costin suggests pressure and flow sensors in to ensure proper delivery of infusing material as shown above. It would have been obvious to one of ordinary skill in the art to modify the invention of Bassuk to include the pressure and flow sensors of Costin to ensure appropriate delivery of infusing material to the patient.

Response to Arguments

7. Applicant's arguments filed 26 August 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the prior art references do not show a controller that is detachable from the MEMS element, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Applicant contends that none of the cited references disclose that a controller is detachable from the MEMS element. All of the cited references show that the controller is somehow connected to the MEMS element. Such a connection is easily detached or broken and can similarly be reattached. Such a limitation cannot impart a structural difference over the references cited. The rejections under 35 U.S.C. §102(b) and (e) are hereby maintained.

In response to applicant's argument that the prior art references do not show that the tubing is medical grade IV or that the container is an IV container, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re*

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Otto, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The limitations regarding the IV tubing and the IV container are referred to in claims 19-22. The Examiner presented new grounds of rejection, as necessitated by Applicant's amendment, to those claims as being anticipated by Guerrero. The Guerrero device is capable of being used in an intravenous situation with IV fluids. The amendment does not impart a structural difference over Guerrero. The rejection under 35 U.S.C. §102(e) is hereby maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Han
Patent Examiner
Art Unit 3763

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March 3, 2005



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